

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Washington, DC 20250

VETERINARY SERVICES (VS) NOTICE 98-12

Subject: Sampling of Animal Serum Shipments for Species Verification

Date: Febuary 9, 1999

To: Port Inspectors, Plant Protection and Quarantine (PPQ)

Directors, PPQ Regions Directors, VS Regions

Assistant to the Deputy Administrator, PPQ

Area Veterinarians in Charge, VS

Director, National Veterinary Services Laboratories (NVSL)

This Notice replaces VS Notices dated December 11, 1992 and July 30, 1996. The purpose of this Notice is to outline the procedures for sampling commercial serum shipments to verify the species of origin.

Several commercial U.S. importers of animal serum have begun to import non-ruminant serum from China and other countries. China is one of the countries affected with several animal diseases, such as foot-and-mouth disease, rinderpest, and hog cholera, which are exotic to the United States. The only animal sera that are allowed to be imported from China are from non-livestock species such as mice, rats, dogs, cats, guinea pigs, and monkeys. To ensure that no sera of other species is being imported, particularly livestock sera, permits are issued with the provision that the serum shipments are subject to random sampling for species verification.

The serum is usually shipped frozen in 500 and 1000 milliliter (mL) plastic containers. The size of the shipment varies between a few liters to over twenty liters. Each shipment must be accompanied by an **original** official certificate endorsed by a full-time, salaried veterinarian from the exporting country confirming that the serum was obtained from healthy animals that had not been inoculated with or exposed to any infectious livestock or avian pathogen. The permit and accompanying certificate are reviewed at the port of entry by U.S. Department of Agriculture (USDA), PPQ officers. The shipment is allowed to proceed to the consignee identified on the permit if the documents are correct.

Prior to the revision of this Notice, all record keeping was maintained by the Animal Products Staff in Riverdale, Maryland. Record keeping will now be the responsibility of the Area Offices. Upon receiving a copy of the permit, the Area Office should contact the permittee to establish a method by which the permittee will notify the Area Office of a shipment's arrival. Every attempt should be made to collect the samples as soon as possible and notify the permittee of the test results. Each permit should have a sampling record attached to it. (See Attachment 1)

Sampling must be done by an Animal and Plant Health Inspection Service representative (i.e., veterinary medical officer or animal health technician). A minimum of two shipments, at least one every 6 months, must be sampled during the duration of the permit. If all shipments are received during the last 6 months of the permit's duration, then two shipments must be selected from these shipments. The samples must be randomly selected upon arrival at the importer's establishment. Use the "95 Percent Confidence Table" (See Attachment 2) to determine the number of containers from which serum is to be collected. A 3 mL sample must be taken from **each** container of **thawed** serum; do not scrape frozen serum off the top of the container. **Each** sample should be transferred to a red-top test tube and the test tube clearly identified (i.e., include lot and batch number from which the sample was collected).

Send the samples to:

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USDA, APHIS, VS, NVSL

Attn.: BMPS 1800 Dayton Road Ames, Iowa 50010

A completed VS Form 10-4, Specimen Submission, must accompany each shipment. Under Block 7, the *Examination Requested* is species verification. Under *Additional Data*, block 22, include the permit number and state that a copy of the test results should be sent to the Animal Products Staff.

User fees are not to be charged for the sample collection or travel.

If the test results determine that the sample is not from the species designated on the permit, the shipment must either be destroyed or returned to the shipper. If the importer elects to have the shipment destroyed, the Animal Products Staff will coordinate the issuance of a destruction order.

Questions should be referred to Dr. John Cougill, Animal Products Staff, Riverdale, Maryland, at Area Code (301) 734-3277.

/signed/

Alfonso Torres Deputy Administrator Veterinary Services

Attachments

ANIMAL SERUM PERMITS SAMPLING RECORD

Company/Importer:	Permit No.:
	Issued:

Ports of Entry	Date	Results	Do Not Need to Sample Again Before:

95 Percent Confidence Table

Total Number of Containers (any volume)	Number of Containers to be Sampled
in Shipment	
< 19	All
19	18
20	19
25	22
30	25
35	28
40	30
45	33